NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ORTHO-MCNEIL PHARMACEUTICAL, INC., Plaintiff, v. MYLAN LABORATORIES INC., et al., Defendants.	Civil Action Nos. 04-1689 and 06-757 Consolidated Cases **OPINION**

CHESLER, District Judge

This matter comes before the Court on the motion by Plaintiff Ortho-McNeil Pharmaceutical, Inc. ("Ortho") for partial summary judgment, pursuant to FED. R. CIV. P. 56, on the § 112 invalidity defenses of Defendants Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan"). For the reasons stated below, Ortho's motion for summary judgment is **GRANTED**.

BACKGROUND

This is a patent infringement case brought under the Hatch-Waxman Act. Plaintiff Ortho claims that, on April 23, 1985, the United States Patent and Trademark Office ("PTO") issued United States patent number 4,513,006 (the "'006 patent") to McNeilab, Inc. as assignee of inventors Bruce E. Maryanoff and Joseph F. Gardocki. (Compl. ¶ 10.) McNeilab is Ortho's corporate predecessor. (Id.) The claims of the '006 patent cover the drug topiramate,

pharmaceutical compositions containing topiramate, and a method of using topiramate to treat convulsions. (Id. ¶ 11.) Ortho holds an approved New Drug Application ("NDA"), under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 335(a), for topiramate tablets and topiramate capsules, which are marketed in the United States as the anticonvulsant TOPAMAX®. (Id.) The PTO has granted an interim extension of the '006 patent for one year, and Ortho has applied to have it extended further, possibly until as late as September 26, 2008. (Compl. ¶ 13.) A fuller recounting of the background to this case is given in this Court's Opinion of May 30, 2006 and will not be repeated here.

In its moving brief for the instant motion, Ortho contended that summary judgment on Mylan's § 112 defenses should be granted because Mylan has offered no evidence of nonenablement or indefiniteness. In opposition, Mylan pointed to the evidence cited in ¶¶ 45-68 of the Final Pretrial Order. In reply, Ortho presented arguments on the legal sufficiency of that evidence. On May 15, 2006, this Court held oral argument on both Ortho's motion for summary judgment on the inequitable conduct defense and the instant motion. At the hearing, Mylan contended that it had not had an opportunity to respond to Ortho's arguments in the reply brief, and this Court allowed the parties to submit supplemental briefing on these issues, which they did.

LEGAL STANDARD

I. Summary Judgment

Summary judgment is appropriate under FED. R. CIV. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S.

317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).[1]

"When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Property, 941 F.2d 1428, 1438 (11th Cir. 1991)). "[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." Celotex, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that

[1] In patent cases, a district court applies its circuit's law of summary judgment. See CollegeNet Inc. v. ApplyYourself Inc., 418 F.3d 1225, 1230 (Fed. Cir. 2005).

creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990); see also FED. R. CIV. P. 56(e) (requiring nonmoving party to "set forth specific facts showing that there is a genuine issue for trial"). "A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial." Gleason v. Norwest Mortg., Inc., 243 F.3d 130, 138 (3d Cir. 2001).

If the nonmoving party has failed "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial, . . . there can be 'no genuine issue of material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23).

II. Enablement

Because [a] patent is presumed valid, clear and convincing evidence must support a conclusion of invalidity. 35 U.S.C. § 282; Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1253 (Fed. Cir. 2004). The party asserting invalidity bears the burden of establishing it. 35 U.S.C. § 282.

The first paragraph of § 112 requires that a patent's specification sufficiently enable one skilled in the art to make and use the claimed invention. It states that a specification "contain a written description . . . of the manner and process of making and using [the invention] . . . in such

full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . ." 35 U.S.C. § 112. The Federal Circuit has construed § 112, paragraph 1, to require that a patent specification enable "those skilled in the art to make and use the full scope of the claimed invention without undue experimentation." Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC, 381 F.3d 1142, 1155 (Fed. Cir. 2004) (internal citations omitted).

"Enablement is a question of law involving underlying factual inquiries." Falkner v. Inglis, 448 F.3d 1357, 1363 (Fed. Cir. 2006). To meet the enablement requirement, "[a] patent need not disclose what is well known in the art." In re Wands, 858 F.2d 731, 735 (Fed. Cir. 1988). Nor does it require the claim specification to obviate the need for all experimentation in order to implement the patent's teachings. Experimentation needed to practice the invention must not, however, be "undue experimentation." Id. at 736-37 (citation omitted).

"Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." Id. at 737. The Federal Circuit weighs these factors: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id.

DISCUSSION

I. Plaintiff's Motion for Summary Judgment on the § 112 Invalidity Defense.

As described above, Ortho initially moved for partial summary judgment on Mylan's

invalidity defenses under §§ 101, 102, and 112, contending that Mylan had offered neither argument nor evidence to support a showing of invalidity. (Pl.'s Br. 3.) Mylan responded that it no longer claims that the '006 patent is invalid under §§ 101 or 102, but that the factual basis for its § 112 claims is set forth at ¶¶ 45-68 of the Final Pretrial Order. (Defs.' Opp. Br. 2.) In reply, Ortho argued that Mylan's § 112 defenses should be barred as untimely, and that, even if this Court were to consider the evidence described in the Final Pretrial Order, Mylan has failed to establish a genuine issue as to any material fact under § 112. (Pl.'s Reply Br. 2, 6.) This Court gave the parties leave to submit supplemental briefing on the subject of this dispute.

The enablement dispute concerns claims 6, 7, and 8, the claims which make reference to the use of topiramate for the treatment of convulsions. Claims 7 and 8 are dependent on claim 6, the claim on which the dispute centers, which states: "A pharmaceutical composition effective for the treatment of convulsions comprising an anticonvulsantly effective amount of a sulfamate of claim 1 and a pharmaceutically-acceptable carrier." ('006 Patent, col. 8, ll: 6-9.) Mylan argues that the '006 patent is invalid under § 112, paragraph 1 because, at the time of filing, one of ordinary skill in the art would not be able to determine what an "anticonvulsantly effective amount" was without undue experimentation.

To support its position, Mylan relies on a meritless interpretation of the deposition testimony provided by Ortho's medical expert, Dr. Privitera. Mylan contends that Dr. Privitera conceded that the patent does not teach one of ordinary skill in the art to make and use topiramate. Mylan then attempts to use the fact that Ortho engaged in extensive clinical trials to satisfy FDA requirements as evidence that undue experimentation was required to enable use of the invention.

Mylan's arguments are unpersuasive on several grounds. Most importantly, Mylan consistently misreads Dr. Privitera's deposition testimony. First, Mylan cites this exchange:

> Q. As a treating physician with a great deal of experience in epilepsy treatment, is there anything in [] claim [6] itself that would inform you how much topiramate would comprise an anti-convulsantly effective amount?
>
> A. Not in that claim. Those would have to be clinical trials to determine what the appropriate dose was.

(Defs.' Suppl. Br. 3, quoting Privitera Dep. 111:7-14, July 15, 2005.) Dr. Privitera's answer does not have the meaning that Mylan asserts. Dr. Privitera does not state that the patent as a whole does not enable treatment of convulsions with topiramate. Rather, although the questioner asked about the effective amount of topiramate, Dr. Privitera's answer refers only to determining the "appropriate" dose, not an anticonvulsantly effective dose. Mylan does not provide a basis to conclude that Dr. Privitera understood "appropriate dose" to be synonymous with "anticonvulsantly effective dose."

Moreover, Dr. Privitera expressly limited the scope of his answer to claim 6. He did not state that the specification, or the teaching of the patent as a whole, failed to enable use of an anticonvulsantly effective amount. Because § 112, paragraph 1 requires that the specification, not the claim, be enabling, any statement about a claim alone cannot show invalidity under § 112, paragraph 1.

In quoting the transcript, Mylan then omits a key statement in which Dr. Privitera explained what he meant by "clinical trials to determine what the appropriate dose was:"

> Q. And would you also need to conduct clinical trials to determine where in that range an affective [sic] amount would be?
>
> A. This refers to unit dosages of a compound and what I was referring to in the

> clinical trials was finding an optimal dose, daily dose, of the drug effective against epilepsy.

(Privitera Dep. 112:4-10, July 15, 2005.) Here Dr. Privitera makes clear that clinical trials are used to find the *optimal* dose, not the *anticonvulsantly effective* dose.

In Mylan's next block of quotes, Dr. Privitera continued to speak about using clinical trials to find an optimal dose:

> Q. Is there anything in the patent that tells you specifically what dose to use in people with epilepsy?
>
> A. No, there's nothing in the patent that tells you specifically what dose to use in people with epilepsy.
>
> Q. All right. So how would you know that?
>
> A. You would then perform clinical trials to find an optimal dose, but you can use animal studies to get a range of doses.

(Defs.' Suppl. Br. 4, quoting Privitera Dep. 112:22-113:11, July 15, 2005.) Again, Dr. Privitera made clear that clinical trials are used to find the optimal dose. Moreover, § 112 would not require that the patent tell specifically what dose to use with people with epilepsy. Rather, it requires that the patent enable one of ordinary skill in the art to treat convulsions using an anticonvulsantly effective amount, without undue experimentation. Dr. Privitera's statements may not reasonably be construed to support the inference that the patent failed this legal test.

Dr. Privitera's deposition testimony provides evidence supporting the unremarkable proposition that clinical trials are used to determine optimal dosages. It does not support the inference that one of ordinary skill in the art would not understand from the specification how to use topiramate to treat convulsions with an anticonvulsantly effective amount. No reasonable jury could hear this evidence and find in favor of Mylan on the issue of nonenablement.

In its supplemental brief, Mylan contends that, applying the Wands analysis of undue experimentation, it has offered "solid evidence" that undue experimentation would have been required. (Defs.' Suppl. Br. 7.) Conspicuously absent from the analysis that follows is any citation to the record. Instead, Mylan offers argument based on the faulty interpretation of Dr. Privitera's deposition testimony discussed above.[2] Mylan offers no evidence whatever that one of ordinary skill in the art would have to engage in undue experimentation to practice claims 6, 7, or 8 of the '06 patent.

Mylan has therefore not pointed to any evidence that the '006 patent is invalid under § 112, paragraph 1, due to failure to enable one of ordinary skill in the art to make and use the invention without undue experimentation. Because Mylan would bear the burden of proof of invalidity at trial, this constitutes a complete failure of proof, and Ortho is entitled to judgment as a matter of law. Celotex, 477 U.S. at 323. Partial summary judgment will be granted in Ortho's favor on the issue of Mylan's defense of invalidity due to nonenablement.

It is worth noting that the Federal Circuit addressed a similar case in CFMT, Inc. v. YieldUp Int'l Corp., 349 F.3d 1333, 1338 (Fed. Cir. 2003). In CFMT, the defendant based its argument for invalidity due to nonenablement on the problems that the patentee encountered in developing a commercial embodiment of the invention. Id. at 1336. The district court had concluded that the patent was invalid because it did not enable an embodiment which met commercial standards. Id. at 1338. The Federal Circuit reversed, holding that:

---

[2] The only other evidence of record that Mylan points to is a quote from Ortho's expert Dr. Kupfergerg on predicting human metabolism rates from animal data. (Defs.' Suppl. Br. 9.) This is not evidence that one of ordinary skill in the art would have to engage in undue experimentation to use an anticonvulsantly effective dosage of topiramate.

> the district court set the enablement bar too high. Enablement does not require an inventor to meet lofty standards for success in the commercial marketplace. Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect. . . . The lengthy experiments [] do not show nonenablement because the inventors undertook that work to satisfy [the patentee's] particular commercial requirements, not to show enablement of the scope of the claimed inventions.

Id. at 1338-1339. Similarly, in the instant case, the lengthy experiments needed to obtain FDA approval were done to satisfy Ortho's particular commercial requirements. Section 112, paragraph 1, does not require enablement of commercial success, absent a claim limitation to that effect. Mylan has not argued here that the claims contain limitations requiring commercial viability. Mylan asks this Court to set the enablement bar too high.

Because this Court has determined that Ortho's motion for summary judgment will be granted, it need not reach Ortho's request that Mylan's nonenablement defense be dismissed for untimeliness.

In its opposition brief, Mylan also contends that claims 6, 7, and 8 are invalid under 35 U.S.C. § 112, paragraph 2, due to indefiniteness. As above, as to the factual basis for the indefiniteness argument, Mylan refers to ¶¶ 45-68 of the Final Pretrial Order. (Defs.' Opp. Br. 2.) Examination of this section of the Final Pretrial Order shows indefiniteness expressly addressed only by a single conclusory statement in ¶ 68.

Mylan begins its supplemental brief by recognizing that at issue is summary judgment on "Mylan's § 112 invalidity defenses." (Defs.' Suppl. Br. 1.) Despite this acknowledgment, through the use of the plural, that more than one § 112 defense is at issue, the brief addresses the issue of nonenablement alone and does not argue indefiniteness. As above, Mylan has pointed to

no evidence that claims 6, 7, or 8 are invalid for indefiniteness, pursuant to 35 U.S.C. § 112, paragraph 2. Moreover, Mylan has failed to articulate even an argument of indefiniteness. Because Mylan would bear the burden of proof of invalidity at trial, this constitutes a complete failure of proof, and Ortho is entitled to judgment as a matter of law. Celotex, 477 U.S. at 323. Partial summary judgment will be granted in Ortho's favor on the issue of Mylan's defense of invalidity due to indefiniteness.

CONCLUSION

For the reasons stated above, as to Mylan's § 112 invalidity defenses, Ortho has demonstrated that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). Ortho's motion for partial summary judgment on Mylan's § 112 invalidity defenses is granted.

s/ Stanley R. Chesler
United States District Judge

Dated: October 3, 2006